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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,978	02/24/2004	Ramesh Dandala	2003-015	6953

7590
Jay R Akhave
845 Pomello Dr
Claremont, CA 91711

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,978

Applicant(s)

DANDALA ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/04;12/22/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1273587 or 4559334.

In EP 1273587 (this is the English language version; original publication date as noted in field (87) was 10/25/2001), see the working examples.

In 4559334, where the product of example 14 is called “crystalline like amorphous product.” It is hard to understand exactly what that actually means, since amorphous means non-crystalline. The most likely explanation is that that material is largely amorphous, but that it has some crystalline material present, which would give it some “crystalline like” character. Applicants need to show that either a) the “crystalline” is in error, or that the crystalline material present is a different form. It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially

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identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, or 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Note also that MPEP 2112 states:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

In this case, the "unknown property" is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

Again, the "CHARACTERISTIC" which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is.

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The only difference is a characteristic about which the reference happens to be silent. See also *Ex parte Anderson*, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (page 1253). The "properties" branch of that statement applies here.

Finally, even if the forms were different, claim 7 would still be anticipated. The claim covers aqueous solutions, and once the material is dissolved in solution, the same solution results.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

Specifically:

It is not at all clear what applicants actually have here. The description of the material in the specification appears at odds with the representations made in the Request for Interference.

According to the specifications of both 10634978 and 10976230, applicants have exactly only and one thing, viz, Form B. This Form B is according to both specifications, a sesquihydrate. Accordingly the claims are not correct, as the material is not cefdinir but cefdinir sesquihydrate.

However, according to the Request, there are actually two compositions of matter present, that of claims 1-7, which the examiner will denote as X, and that of claims 8-11, which the examiner will denote as Y. Applicants consider these things to be patentably distinct, as X is listed as corresponding to the count, and Y is not. If these were not patentably distinct, then both would correspond to the count. MPEP 2301.03 states, "If the claimed invention of either party is patentably distinct from the claimed invention of the other party, then there is no interference-in-fact. *Nitz v. Ehrenreich*, 537 F.2d 539, 543, 190 USPQ 413, 416 (CCPA 1976)." According to this chart, Y does not correspond to the interfering subject matter, and hence is patentably distinct from the interfering subject matter, and hence must be patentably distinct from X, since X does in fact correspond to the interfering subject matter. Thus, X must be patentably distinct from Y. But the specification, as noted above, does not actually describe two patentably distinct things, since it does not describe two things at all. Hence, the rejection under paragraph 1.

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Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear exactly how form B is to be defined. The difficulty is that 10634978 and 10976230 have different descriptions. 10634978 has 25.6 ± 2 and 10976230 has 26.2 ± 2 . These numbers are not only significantly different -- more than half a degree --, but the ranges do not even overlap. That is, regardless of what number is obtained in a measurement, it will fail to meet the definition of Form B in at least one of 10634978 or 10976230. Moreover, this is not the only difference. 10634978 has 20.9 ± 2 , and 10976230 has 21.2 ± 2 . While these do have some overlap, it is only the ranges the overlap (that is, neither range overlaps the other number), and some numbers i.e. 20.8, 20.7, 21.3 and 21.4 will meet one definition and not the other. And a third number is different as well (22.2 vs. 22.3). These discrepancies cast doubt on whether or not the numbers are said to be accurate at all.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. As written, claim 4 has periods in the middle of the claim. Page 16, lines 21 and 22 should have the periods "raised" to the dot used for adducts or salts, or alternatively removed.
2. "Preferably" (claims 5 and 6) is improper alternative language (In re Kingston, 65 USPQ 371).

3. **Claim with the IR data is indefinite. One cannot tell how to prepare the IR spectrum, because no medium was given. That is, the IR spectrum is known to vary somewhat according to whether it is a solution (and in what solvent?), a Nujol mull, a KBr disc, the individual crystal, etc. Thus, one can never be sure that a given sample does not fall within the claim, as there is always the possibility that choosing the e.g. correct solvent will actually give this pattern. The information appears to be missing from the specification.**

Request for interference

Applicants have submitted with this case a document entitled "Request to declare and Interference". This material is confusing. No application number is given in the heading for this paper. Instead, it is labeled with Attorney docket number "7893-12". The examiner cannot locate a case corresponding to such a number. The remarks refer to "declaration and exhibits prepared for parent application of no. 10634978", but 10634978 has no parent. The document refers to 23 claims, but neither 10634978 nor its CIP 10976230 have 23 claims. Further, the Chart B description of the claims does not correspond to the claims in either case. For example, Chart B refers to claim 13 as being a composition. However, 10634978 has no claim 13, and in 10976230, claim 13 is drawn to a process. The examiner concludes that this is a document for an application which has not yet been filed, which is referred to by applicants as "the Dandala application".

In addition, it is not entirely clear that there is interference-in-fact. If all applicants have is Y, and Y does not correspond to the count, then there is no interference-in-fact. To put it differently, if this interference were to be set up as applicants suggest, and applicants were to lose, they would still gain a patent on claims 8-11, which would completely cover

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exactly what their specification says they invented, viz, Form B. That would make the interference proceedings pointless. The PTO will not set up an interference such that even if applicants lose, they will still be able to patent exactly what they have invented.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 11, 13, 14 and 15 of copending Application No. 976230. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The same claims appear in both cases.

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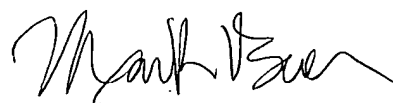
Specification

The abstract is objected to. It states that there is a process, but does not state what the process actually consists of.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mark L. Berch
Primary Examiner
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2/10/06